

Application No. 10/618,362  
Amendment and Reply dated February 27, 2006  
Reply to November 25, 2005 Office Action

## **REMARKS**

### **Amendments to the Claims**

Applicants have amended claims 1-2, 7-9 and 15 and added claim 18 to more particularly point out and distinctly claim the invention. Applicants have cancelled claims 3-6, 10-14 and 16-17 without prejudice to seeking protection on the cancelled subject matter in applications related hereto. None of the amendments adds new matter. Their entry is requested. With the amendments, claims 1-2, 7-9, 15 and 18 are pending.

Applicants have amended claim 1 to recite a method, rather than a composition, for the treatment of asthma comprising the step of administering a composition comprising an NF- $\kappa$ B decoy and a pharmaceutically acceptable carrier. Support for this amendment may be found, for example, on page 31, lines 14-31 and in Example 6 on pages 48-51, of the specification as filed. Applicants have also amended claim 2 to recite a method, rather than a composition, that comprises the nucleotide sequence of SEQ ID NO. 13. Support for this amendment may be found, for example, on page 51, lines 15-20, of the specification as filed. Applicants' amendment of claims 1 and 2 necessitated amendment of dependent claims 7-9 and 15 to recite method claims rather than composition claims and to recite asthma, as necessary in the claims. Applicants have added dependent claim 18, which is directed to a method for treatment of asthma comprising an oligonucleotide having a sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 5. Support for added claim 18 may be found, *e.g.*, on page 15, lines 27-32.

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## **THE OFFICE ACTION**

### **Species Restriction and Election**

The term “an NF-κB decoy” as used in amended, independent claim 1 is a generic term. This is reflected in amended claim 2, which recites the NF-κB decoy comprising the nucleotide sequence of SEQ ID NO: 13. An NF-κB decoy, as defined in the specification, includes specific NF-κB decoys, *e.g.*, the specific decoy of SEQ ID NO. 1. It includes chimera decoys, *e.g.*, the chimera decoy of SEQ ID NO. 5. Thus, added claim 18, which recites the NF-κB decoy comprising oligonucleotides characterized by each those specific SEQ ID NOs, continues indirectly to depend from claim 1.

Applicants confirm their species election of NF-κB for initial examination in this application. Given the Examiner’s list of species (a), (b) and (d) - - all of which applicants believe are NF-κB decoys - - applicants further elect the NF-κB decoy of SEQ ID NO. 13 for initial prosecution in this application.

Claims 1-2, 7-9, 15 and 18 read on the NF-κB decoy of SEQ ID NO. 13.

### **Rejection Under 35 U.S.C. §§ 102(b) and 102(a)**

Claims 1-3, 6, 8-11, 14-15 and 17 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by European Patent 1008352 (the “352 patent”). The Examiner states that the ‘352 patent discloses pharmaceutical compositions comprising an NF-κB and a pharmaceutically acceptable carrier that can be a liposome. The Examiner also states that the

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use of the composition “for treatment of disease” is a future use, and given no patentable weight. In view of the amended claims, applicants traverse.

The ‘352 patent neither teaches nor suggests a method for the treatment and/or prevention of asthma comprising the step of administering a composition comprising an NF-κB decoy. Amended claims 1-2, 7-9, 15 and 18 recite that method. The ‘352 patent generally relates to treatment of brain disorders associated with encephalopathy with an NF-κB decoy. Specifically, the ‘352 patent refers to treating subarachnoid hemorrhage by delivering an NF-κB decoy using a liposome carrier. See the ‘352 patent, page 4, column 5, paragraph [0022]. The ‘352 patent never refers to or suggests a method for the treatment and/or prevention of asthma by administering an NF-κB decoy whether or not in a liposome carrier. Thus, the ‘352 patent does not and cannot anticipate amended claims 1-2, 7-9, 15 and 18. Accordingly, applicants request that the Examiner reconsider and withdraw this rejection.

Claims 1-3, 6, 8-11, 14-15 and 17 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by European Patent 0824918 (the “‘918 patent”). The Examiner argues that the ‘918 patent teaches pharmaceutical compositions comprising an NF-κB decoy and a pharmaceutically acceptable carrier. In view of their amendments to the claims, applicants traverse.

Amended claims 1-2, 7-9, 15 and 18 relate to methods for the treatment and/or prevention of asthma by administering an NF-κB decoy and a pharmaceutically acceptable

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carrier. One embodiment of applicants' claimed invention is a method using a liposome carrier. The '918 patent does not disclose or teach that method.

The '918 patent refers to methods of treating ischemic heart disease, cancer and cachexia. The '918 patent does not disclose or teach a method for the treatment and/or prevention of asthma by administering a composition comprising an NF-κB decoy and a pharmaceutically acceptable carrier. Thus, the '918 patent does not and cannot anticipate amended claims 1-2, 7-9, 15 and 18. Accordingly, applicants request that the Examiner reconsider and withdraw this rejection and allow amended claims 1-2, 7-9, 15 and 18.

Claims 1-3, 6, 8-11, 14-15 and 17 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by United States patent 6,262,033 (the “‘033 patent”). The Examiner argues that the ‘033 patent discloses pharmaceutical compositions comprising an NF-κB decoy and a pharmaceutically acceptable carrier. In view of the amended claims, applicants traverse.

Amended claims 1-2, 7-9, 15 and 18 relate to methods for the treatment and/or prevention of asthma by administering an NF-κB decoy and a pharmaceutically acceptable carrier. The ‘033 patent refers to methods of treating cancer and cachexia. The ‘033 patent does not disclose or suggest a method for the treatment and/or prevention of asthma by administering an NF-κB decoy and a pharmaceutically acceptable carrier. Thus, the ‘033 patent does not and cannot anticipate amended claims 1-2, 7-9, 15 and 18. Accordingly, applicants request that the Examiner reconsider and withdraw this rejection and allow amended claims 1-2, 7-9, 15 and 18.

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**Rejection Under 35 U.S.C. § 103(a)**

Claims 7 and 16 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over '352 in view of U.S. patent 5,225,212 (the "212 patent"). The Examiner argues that the '352 patent teaches an NF-κB decoy-based composition, wherein the pharmaceutical carrier is a liposome. The Examiner acknowledges that '352 patent does not teach a composition comprising a hydrophilic polymer. The Examiner, however, contends that the '212 patent teaches liposome-based compositions derivatized with hydrophilic polymers. In view of the amended claims, applicants traverse.

Amended claim 7 recites a method of treating asthma. Applicants have cancelled claim 16 as duplicative of claim 7. As explained above, the '352 patent does not teach or suggest the treatment of asthma. It relates solely to the treatment of brain disorders. See the '352 patent, column 2, paragraph [0007]. The '212 patent does not remedy that deficiency. Indeed, nothing in the '212 patent teaches or suggests the use of any composition for use in treating asthma. In sum, therefore, the combination of the '352 patent and the '212 patent, even if it were suggested, which applicants do not admit, does not render applicants' amended claim 7 unpatentable. Accordingly, applicants request that the Examiner reconsider and withdraw this rejection and allow amended claim 7.

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**CONCLUSION**

In view of the foregoing remarks and amendments, applicants request that the Examiner reconsider amended claims 1-2, 7-9, 15 and 18 now pending in this application and allow these claims. If the Examiner believes that a telephone conference would expedite allowance of this application, he is invited to telephone the undersigned at any time.

Respectfully submitted,



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